

USSN 09/554,533
Atty Docket No. 238/086US**REMARKS****Election/Restriction**

Applicants note that the election/restriction set forth does not conform to the one discussed with Mr. Butler on July 5, 2006. However, to facilitate prosecution, Applicants respond to the current election/restriction requirement. Applicants' response should not be taken as acknowledgement or acceptance of the Examiner's statement that "claims 66-69 are obvious variation [sic] of the instant SEQ ID NO: 29." Office Action dated July 12, 2006, page 2.

Objections

Applicants have attended to the three informalities set forth by the Examiner and, as such, Applicants respectfully request the Examiner withdraw the objections.

35 U.S.C. § 101

Claims 55-62, 66-71, and 74-75 stand rejected by the Examiner because they cover a naturally-occurring peptide or polypeptide. However, the Examiner does not point to any naturally-occurring peptide or polypeptide that falls within the scope of the claims. As a result, Applicants request that either the Examiner specify which naturally-occurring peptide or polypeptide he is referring to or withdraw the rejection.

35 U.S.C. § 112, second paragraph

The Examiner asserts that claims 56, 58, 61, 67, and 68 are indefinite as they set forth Xaa₂ is Ser, Xaa₃ is Asp and Xaa₂₈ is Ala. These claims are indefinite in the Examiner's view because they recite non-elected sequences (see, e.g., Office Action dated July 12, 2006, page 4). Two pages earlier, the Examiner states that claims 55-62 and 66-69 "are considered to be drawn to the elected invention" (see, Office Action dated July 12, 2006, at page 2). Since claims 56,

USSN 09/554,533
Atty Docket No. 238/086US

58, 61, 67 and 68 merely further limit claim 55, which the Examiner acknowledges is drawn to the elected invention, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Claims 70 and 74 are asserted as indefinite because they lack the subject to be administered. Applicant disagree but, to facilitate prosecution, have amended claims 70 and 74 to recite "a subject in need thereof."

Claim 71 is asserted as indefinite because it is not apparent whether or not the insulin is co-administered or administered separately with the compound of claim 55. Applicants submit this rejection lacks any legal basis.. Applicants submit that the scope of the subject matter claimed is clear. Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. See MPEP § 2173.04. The claims do not include a limitation relating to whether the insulin is co-administered or administered separately. Thus, both are clearly within the scope of the claimed invention. Therefore, the rejection is improper and should be withdrawn.

In light of the above, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

35 U.S.C. § 112, first paragraph

The Examiner rejected claims 55-62, 66-69, 70-71, and 74-75 because a "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." (Citing *Regents of the University of California v. Eli Lilly & Co.*, 43 U.S.P.Q. 1398). The Examiner additionally points to M.P.E.P. § 2163 and states that there is insufficient written description where "a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence." The Examiner goes on to state that "current claims 55 and 66 and dependent claims thereto do not describe biological function of the claim [sic] protein." (Office Action dated July 12, 2006, page 7). The Examiner further alleges that without knowing

USSN 09/554,533
Atty Docket No. 238/086US

the assayable biological function of the claimed peptide, the skilled artisan will not know how to characterize and use the claimed peptide, e.g., for treating diabetes.” (Office Action dated July 12, 2006, page 7).

Applicants traverse the rejection. As held in the recent Federal Circuit decision, *Falkner v. Inglis*, “there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.” 448 F.3d 1357, 1366 (Fed. Cir. 2006). Further, as acknowledged by the Examiner himself, and as stated in accordance with M.P.E.P. § 2163, (Office Action dated July 12, 2006, page 6), a generic claimed genus can be adequately described if the disclosure presents a sufficient number of representative species. Claim 55 and its dependent claims set forth the structural features of the inventive peptides. These structural features are described in the specification in detail (see, e.g., at least at pages 17 through 23). In addition to these considerable teachings, the specification describes over sixty specific species of peptides having the structural features recited in the claims and therefore clearly provides adequate written description of the genus being claimed.

Further, contrary to the Examiner’s assertion, the specification discloses numerous *in vitro* and *in vivo* assays for preparing and assessing activity of the inventive peptides (see specification, Examples 1-62 and A-E, pages 31-86). Thus, contrary to the Examiner’s statement, in view of Applicants’ disclosure, the skilled artisan is provided with all the disclosure necessary to characterize and use the claimed peptides. There is no legal requirement that the function of the peptides be recited in the claims and the specification fully describes and enables the claimed invention.

Applicants therefore submit that the rejection is improper and respectfully requests that the Examiner withdraw the rejection.

35 U.S.C. § 102

The Examiner rejected claims 55, 57, 59-60, 62, 66, and 69 under 35 U.S.C. 102(e) as being allegedly anticipated by Young *et al.* (US 6,858,576). Applicants respectfully traverses these rejections because claims 55, 57, 59-60, 62, 66, and 69 are not anticipated by Young *et al.*

USSN 09/554,533
Atty Docket No. 238/086US

Rejection of Claims 55, 57, 59-60 and 62

In rejecting claims 55, 57, 59-60, and 62,¹ the Examiner asserts that Young *et al.* teach an exendin agonist peptide having SEQ ID NO:32 which is asserted to exhibit 100% sequence identity to the peptide of claim 55 (Office Action dated July 12, 2006, pages 8-9). Applicants respectfully disagree with this assertion.

In order for a claim to be anticipated, a reference must teach every element of the claim. MPEP § 2131. That is, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

SEQ ID NO:32 of Young *et al.* sets forth a different sequence from the claimed invention. Claims 55 and dependent claims are drawn to peptides with a length of 38 amino acids. In contrast, SEQ ID NO:32 of Young *et al.* discloses a peptide with a length of 39 amino acids (see, e.g., Young *et al.* at columns 45-46). Further, SEQ ID NO:32 of Young *et al.* differs from the presently claimed peptides by at least the presence of Serine at position 39 of SEQ ID NO:32 (see, Young *et al.* at columns 45-46). As such, SEQ ID NO:32 of Young *et al.* does not share 100% sequence identity to the claimed peptides and therefore does not describe each and every element of the claims. Applicants respectfully submit that the rejection is improper and requests that the Examiner withdraw the rejection.

Rejection of Claims 66 and 69

In rejecting claims 66 and 69,² the Examiner asserts that Young *et al.* teach an exendin agonist peptide having SEQ ID NO:6 which is asserted to share 100% sequence identity to the peptide set forth in claim 66, when residues 2 and 3 are Glycine and Glutamine, respectfully (Office Action dated July 12, 2006, page 9). Applicants respectfully disagree with this assertion.

SEQ ID NO:6 of Young *et al.* differs from the claimed invention. Claim 66 recites a peptide of 38 amino acids. In contrast, SEQ ID NO:6 of Young *et al.* disclose peptides with a

¹ Claims 57, 59-60 and 62 depend from claim 55.

² Claim 69 depends from claim 66.

USSN 09/554,533
Atty Docket No. 238/086US

length of 39 amino acids (Young *et al.* at columns 27-28). Moreover, unlike the claimed peptides, SEQ ID NO:6 of Young *et al.* has a Serine at position 39. Young *et al.* at columns 27-28. Furthermore, SEQ ID NO: 6 of Young *et al.* differs in having a Leucine at position 14. Considering these sequence differences, claims 66 and 69 are not anticipated by Young *et al.* Therefore, Applicants submit that the rejection is improper because Young *et al.* does not describe each and every element of the claims. In light of the above, Applicants request that the Examiner withdraw the rejection.

35 U.S.C. §103

The Examiner rejected claims 55, 57, 59-60, 62, 66, 69-71, and 74-75 under 35 U.S.C. 103(a) as being allegedly unpatentable over Young *et al.* (Office Action dated July 12, 2006, pages 9-10). The Examiner acknowledges that Young *et al.* does not set forth the working example or claim the method of treating a diabetes state comprising administering to a subject the above-mentioned exendin agonist peptide.

In formulating the rejection under 35 U.S.C. 103(a), the Examiner asserts that one of ordinary skill in the art at the time the invention was made would have the requisite motivation to develop a method of treating diabetes mellitus in a subject comprising administering to a subject an exendin agonist peptide (e.g., SEQ ID NO:29). Moreover, the Examiner asserts that Young *et al.* teach the usefulness of exendin agonist peptides in the treatment of diabetes. Office Action dated July 12, 2006, page 10.

Applicants traverse the rejection. As discussed above, the peptide sequences relied upon by the Examiner disclosed in Young *et al.* do not anticipate the claims. The Examiner has provided no evidence whatsoever that Young *et al.* disclose or suggest the claimed peptides let alone disclose or suggest administration of a therapeutically effective amount to a subject in need thereof. As such, Applicants respectfully submit that the rejections of claims 55, 57, 59-60, 62, 66, 69-71, and 74-75 under 35 U.S.C. 103(a) are improper.

In light of the above, Applicants respectfully request that the Examiner withdraw the rejections under 35 U.S.C. 103(a).

USSN 09/554,533
Atty Docket No. 238/086US**Conclusion**

In view of the foregoing arguments and amendments, each of the presently pending claims is believed to be in immediate condition for allowance. All of the stated grounds of rejection or objection have been traversed, accommodated, or rendered moot. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and objections and to pass this application to issue.


With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants believe that the present application is now in condition for allowance. The Examiner is encouraged to call the undersigned to discuss any issues related to the prosecution of the instant application.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Respectfully submitted,
AMYLIN PHARMACEUTICALS, INC.

Dated: 9-Oct-06

By: 
Dianne Rees, Ph.D.
Registration No. 45,281

AMYLIN PHARMACEUTICALS, INC.
9360 Towne Centre Drive
San Diego, CA 92121
Telephone: 858.552.2200
Facsimile: 858.552.1936